DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 17, 2014

Pinnacle Spine Group, LLC
Ms. Rebecca K Pine
Official Correspondent
1601 Elm Street, Suite 300
Dallas, Texas 75201

Re: K143488
Trade/Device Name: InFill™ Graft Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name:
Regulatory Class: Class II
Product Code: FMF
Dated: December 4, 2014
Received: December 8, 2014

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143488

Device Name

InFill™ Graft Delivery System

Indications for Use *(Describe)*

The InFill™ Graft Delivery System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Pinnacle Spine Group, LLC
DATE PREPARED:	December 4, 2014
CONTACT PERSON:	Rebecca K Pine 1601 Elm Street, Suite 300 Dallas, TX 75201 Phone: 760.809.5178 Fax: 760.290.3216
TRADE NAME:	InFill™ Graft Delivery System
COMMON NAME:	Piston Syringe
CLASSIFICATION NAME:	Piston Syringe
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 880.5860
PRODUCT CODE	FMF
PREDICATE DEVICES:	InFill™ graft Delivery System (K121476)

Substantially Equivalent To:
The modified InFill™ Graft Delivery System is substantially equivalent in intended use, principal of operation and technological characteristics to the InFill™ Graft Delivery System cleared under premarket notification K121476

Description of the Device Subject to Premarket Notification:
The modified InFill™ Graft Delivery System is comprised of a disposable medical piston syringe, a cannulated applicator tip and accessories for mixing bone graft materials and filling of the system. The modified InFill™ Graft Delivery System is provided sterile, for single use only.

Indication for Use:
The InFill™ Graft Delivery System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site.

Technical Characteristics:
The modified InFill™ Graft Delivery System has the same technological characteristics and is similar in overall design, materials and configuration compared to the current InFill™ Graft Delivery System as shown in the table below.

Section 6 510(k) Summary

	Modified InFill™ Graft Delivery System	InFill™ Graft Delivery System (K121476)
Materials	SAME	Medical grade polymers
Method of filling	SAME	Front-loaded via barrel
How supplied	SAME	Sterile, single use only
Syringe		
Syringe type	SAME	Piston
Plunger Actuation	SAME	Screw
Principle of operation	SAME	Facilitates delivery of bone graft material.
Material use	SAME	Bone graft materials
Bone graft pre-loaded	SAME	No
Tip type	SAME	Luer lock
Syringe Volume	SAME	12cc
Barrel markings	SAME	Milliliter, graduated
Barrel transparency	SAME	Clear
Cannula		
Cannula length	300mm 275mm 150mm	275mm (10.8 in)
Cannula tip	SAME	Smooth, atraumatic
Marking	SAME	No
Cannula OD	3.5mm 4.8mm 8.0mm	4.8mm
Hub	SAME	Threaded screw
Accessories		
Mixing accessories	SAME	Mixing plunger, closed syringe cap (optional)
Filling accessories	SAME	Funnel, stand (optional)
Graft removal accessory	SAME	Stylet (optional)

Performance Data:

All necessary testing has been performed for the InFill™ Graft Delivery System to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device design was qualified through the following tests:

- Simulated Use Testing

- Volume Verification
- Maximum Force Verification
- Force to Dispense Verification
- Separation Force Testing
- Liquid Leak Testing

The modified InFill™ Graft Delivery System met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:
The Indication/Intended Use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The modified InFill™ Graft Delivery System is found to have a safety and effectiveness profile that is similar to the predicate device and is determined by Pinnacle Spine Group LLC, to be substantially equivalent to the InFill™ Graft Delivery System (K121476).